SRTR Review Committee Meeting Minutes

Teleconference

April 27, 2021, 10:00 AM - 2:15 PM CDT

Voting Members:	**Ex-Officio Members:**	**SRTR Staff:**
Roslyn Mannon, MD (Co-Chair)	Shannon Dunne, JD (HRSA)	Ryutaro Hirose, MD
Jeffrey Orlowski, MS, CPTC (Co-Chair)	Alexandra Glazier, JD, MPH (OPTN-POC)	Larry Hunsicker, MD
Kiran Khush, MD	Jonah Odim, MD (NIH)	Ajay Israni, MD, MS
Chris Zinner	Darren Stewart, MS (OPTN/UNOS)	Bertram Kasiske, MD, FACP
Richard Knight, MBA	Rachel Patzer, PhD (OPTN-DAC)	Donald Musgrove, PhD
Brent Logan, PhD		Caitlyn Nystedt, MPH, PMP
James Markmann, MD, PhD	**HRSA:**	Nicholas Salkowski, PhD
Sumit Mohan, MD, MPH	Chris McLaughlin	Cory Schaffhausen, PhD
James Pittman, RN, MSN	Adriana Martinez	Jon Snyder, PhD, MS
	Shannon Tait	Andrew Wey, PhD

Welcome and opening remarks

Co-Chair Dr. Roslyn Mannon called the SRTR Review Committee (SRC) to order. She took roll call and reviewed the agenda. Dr. Mannon reminded everyone of conflict-of-interest management and proceeded with the agenda.

Approval of the minutes

Dr. Mannon requested an approval of the SRC January and February 2021 meeting minutes. The voting members approved the minutes without dissent**.**

Reports from the subcommittees

Mr. Richard Knight, co-chair of the Patient and Family Affairs (PFA) Subcommittee, said its first meeting was productive. He overviewed the variety of transplant patient representatives. Dr. Allyson Hart explained to members the relationship between the Health Resources and Services Administration (HRSA), SRTR, and the Organ Procurement and Transplantation Network (OPTN). Members were told about the role of patients in supporting transplant work. Mr. Knight said the advisory role was designed to help flesh out ideas important to patients and focus on metric development. He recommended preparing a tentative agenda that would reflect topics covered by PFA members for the consensus conference scheduled in July 2022.

Dr. Ryutaro Hirose asked how the subcommittee would reach out to the spectrum of patients and potential candidates. Mr. Knight said the subcommittee would seek to include geographic and racial diversity in the planned focus groups and contact other organizations for appropriate organ transplant representation. Dr. Mannon suggested that the subcommittee include children and

representation from different pediatric disease groups, and Dr. Jonah Odim advised representation from the non-renal space, because other organs do not have the Medicare safety net.

Chris Zinner, co-chair of the Human-Centered Design (HCD) Subcommittee, reviewed its first meeting. He reviewed the membership, which consists of academic and industry designers with experience in the health and transplant fields. In the first meeting, Dr. Cory Schaffhausen highlighted recent SRTR projects. The committee aims to focus on design critique, giving feedback on SRTR information products. The secondary focus is HCD coaching, or coaching SRTR to continuously engage different audiences for different information products as part of the design process. In the upcoming June meeting, the subcommittee plans to focus on developing a data query system. While no transplant patients are on the subcommittee, Mr. Zinner said they would collaborate with the Patient and Family Affairs Subcommittee.

Developing a plan for handling COVID-19 in the PSR/OSRs

Dr. Andrew Wey said SRC spent a lot of time discussing COVID-19 in the last year, taking an ad hoc approach due to its emergent nature. Now the focus is to develop a framework for determining appropriate SRTR reporting metrics in the COVID-19 era. One framework is the philosophical approach, which focuses on the reasons for changing public reporting due to COVID-19. The second is a data-based framework, which empirically describes the effect of COVID-19 and how it could affect the program-specific reports (PSRs). In its first meeting, the Analytical Methods Subcommittee found it difficult to accurately define the question of interest and identify a data source to adequately address that question. Therefore, the subcommittee concluded that a data-based framework for modifying PSRs is not practical.

Dr. Wey focused on the philosophical framework, explaining three options and their implications. The first was public reporting-captured outcomes during specific periods. While COVID-19 may confound program-specific effects, the PSR/OSRs only describe outcomes after adjusting for known risk factors. Despite public health disasters resulting in geographically variable effects in the last 20 years, public reporting wasn't modified or stopped. This would mean no censorship for the COVID-19 era.

Second, COVID-19 changed the practice of transplant, precluding meaningful public reports, partly because changes couldn't be accounted for in clinical practice. However, it would be difficult to reconcile previous changes in clinical practice that didn't result in changes in public reporting. This option does not indicate when to resume public reporting. The COVID-19 portion would be indefinitely carved out, with no plan for integrating post-pandemic follow-up.

Third, healthcare providers adapted to COVID-19 within a couple of months, which suggested that the first few months after the national declaration of emergency should be removed. Reports would state the period removed, reason for the removal, and that subsequent follow-up wouldn't be removed. This option would carve out the first quarter of COVID-19 (March 13 to June 12, 2020), which was acceptable to SRTR and the option the community would most likely approve. SRTR proposed this option going forward.

Mr. James Pittman said the community would be more concerned about individual programs and less about the pandemic's disruption to the system as a collective. Dr. James Markmann disagreed,

saying the disruption caused the inability to operate, and the community would understand the decision. Dr. Wey clarified how the carve-out would affect posttransplant outcomes evaluations, noting that patient follow-up would be censored on March 12, 2020. Recipients given transplants from March 13 to June 12, 2020, would not be included in the evaluation cohorts. Transplants after June 12 would be included as normal. Dr. Snyder said that for patients given transplants before the national emergency, any deaths occurring after March 12, 2020, would not be included. If a patient received a transplant after June 12, he or she would be included and followed for outcomes.

Mr. Chris McLaughlin asked if there was a rationale justifying the June 12 end date. Dr. Snyder replied that according to trend data, donor counts and transplant counts for most organs increased by June. Dr. Kiran Khush said a 90-day period was reasonable and that extending it would mean a huge data loss. Mr. Darren Stewart noted that the OPTN was using May 10, 2020, as the end date for different policy analyses. Dr. Larry Hunsicker added that trying to identify a "best day" didn't follow a philosophical framework. Dr. Mannon and Mr. Orlowski favored June over May, because the former showed more variation. Dr. Snyder stated that for organ procurement organization (OPO) metrics, the eligible death donation rate wouldn't change because the 1-year evaluation cohort would already be entirely after June 12, 2020, and the donor yield metric would have the carve-out period because this metric uses a 2-year cohort.

Dr. Mannon called for a vote. All members agreed with implementing a carve-out from March 13 to June 12, 2020.

Presentation of PSR evaluations on SRTR website

Dr. Snyder reviewed the COVID-19 website disclaimer mock-ups. The first example displayed a yellow warning banner above the search results and gave the user the option to learn more about pandemic-related report changes. The banner was a part of a three-level warning system. The second-level warning was a pop-up with patient-friendly verbiage stating that it is difficult to capture how metrics were affected by the pandemic and cautioned the user about program comparison. For the third-level warning, a link in the pop-up led to specific information on how metrics were changed. The yellow warning banner with the same options also appeared when a user viewed an interactive program report or conducted OPO searches.

Dr. Schaffhausen said including the word "change" prompted the user to ask what had changed. He added that a lay person's explanation would be more helpful than technical wording. A shortened version of the original press release was used. Mr. Zinner said the "incremental reveal" would be beneficial to users. Dr. Khush suggested adding the June 12 end date to the pop-up text. Dr. Snyder and Mr. Jeffrey Orlowski agreed. Dr. Hirose urged caution in expanding the text, because the language was already general enough to apply to all metrics. For some cohorts, not all data would resume the way it was after June 12.

Dr. Mannon called for a vote for approval of the general mock-ups. Members agreed with the website changes as proposed.

Update on period-prevalent posttransplant outcomes

Dr. Wey said that the transplant community and previous SRC members advocated for metrics that captured long-term posttransplant survival, given the relevance to patients. Calculating long-term posttransplant survival was difficult due to the delay between transplant and follow-up in an incident-based framework, due to the "incident" cohorts used for posttransplant evaluations. SRTR investigated the possibility of period-prevalent cohorts for reporting posttransplant evaluations. The SRC had approved the transition to a five-year period-prevalent cohort during the April 2020 meeting.

Dr. Wey reviewed the difference between period-prevalent and incident cohorts. Incident cohorts include only recipients given transplants during the entry period. The period-prevalent approach includes any patient with a functioning transplant within a recent two-year evaluation window, regardless of the date of transplant, as long as the patient was within five years of transplant. These cohorts include older transplants but focused on the follow-up during the evaluation window, providing an estimate of short-term and long-term outcomes within a period of recent care at the program.

In a published analysis, Dr. Wey demonstrated that a period-prevalent cohort with five years of follow-up at the time a patient joined the list had a stronger association with subsequent posttransplant outcomes than did one- and three-year evaluations. Therefore, the five-year evaluation period would be more informative for patients at listing.

Dr. Wey said that the OPTN Membership and Professional Standards Committee (MPSC) is revising the rules to identify transplant programs for review. It was considering moving from one-year posttransplant outcomes to 90-day and one-year outcomes, conditional on survival to 90 days. Because of this change, it was a good idea to discuss follow-up periods in PSRs. Dr. Wey explained that the purpose of the 90-day evaluation was to capture early posttransplant outcomes. This is because the rate of graft loss for all organs is initially elevated posttransplant, dropping and stabilizing by 90 days posttransplant. SRTR anticipated that MPSC would advance evaluations for 90-day graft survival, 90-day to one-year graft survival, and five-year graft survival, pending the SRTR's launch of the five-year period-prevalent metrics. Dr. Wey asked if there were any other time frames of interest to transplant programs for quality-improvement purposes.

Members discussed the importance of a five-year follow-up across all organs. Dr. Khush hoped the addition would encourage resources and research on improving long-term outcomes. Dr. Sumit Mohan pointed out that five-year outcomes reflected clinical activity that happened six or seven years before, making it irrelevant to a transplant center today, recognizing that the period-prevalent methodology evaluates only a recent two-year period. Mr. Orlowski agreed, saying it was important to point out that by having multiple outcome points, programs would be evaluated at multiple times, which would be more informative than a single outcome. Dr. Khush said that there might be program concerns that longer-term outcomes would reflect practices at other centers, not the original transplant center. Dr. Hunsicker said the evaluation was less about monitoring centers and more about patient concerns on survival outcomes. Mr. Knight added that the five-year metric would be an improvement, particularly for patients. Mr. Pittman said to consider a three-year time point, because many transplant recipients lose Medicare coverage. Dr. Mohan agreed it was important to monitor potential unintended consequences.

Dr. Wey said SRTR is transitioning the current code base from an incident to a period-prevalent cohort. SRTR would bring technical questions on modifying the model-building process to the next Analytical Methods Subcommittee meeting and will update the SRC on its progress at future meetings.

Website updates

Dr. Snyder said that SRTR is working to make the SRTR website more engaging for both professionals and patients. The first project being undertaken is updating the liver waitlist calculator, a tool that compares outcomes of patients on the liver waitlist at a given transplant program with regional and national outcomes. Dr. Snyder reviewed the mock-up of the updated tool, which was put together by Dr. Schaffhausen. The new version was functionally similar but had a modern, human-centered design. Dr. Schaffhausen remarked that the project was on a compressed timeline. The updated version borrowed from the style derived from a years-long project on the kidney waitlist calculator. The tool was primarily for professionals; a simplified version for patients is a potential project.

Mr. Orlowski asked if creating different versions would be an enormous effort. Dr. Snyder said it fell under the plan of separate pathways for patient and professionals on the SRTR website and that the dual task was manageable. Ms. Alexandra Glazier asked it if was necessary to include DSA as a regional aggregation level on the tool, because DSAs are no longer units of distribution, and advocated for it to be changed. Mr. Pittman said that state aggregation would be better, while Ms. Glazier disagreed. Mr. Knight said DSA as a level could be misleading, because it is no longer used in allocation policy. Mr. Zinner suggested usability testing to assess needs and find out what resonates with patients and professionals. Dr. Snyder said swapping DSA and region with a radius will be considered. Dr. Ajay Israni suggested adding the SRTR main phone number to the page for patient questions. Mr. Zinner said that a video tutorial or chatbot would also be helpful.

Next, Dr. Snyder discussed the transplant data query system tool under development. SRTR partners with the OPTN every year to create an annual data report (ADR), which is published in the *American Journal of Transplantation* (*AJT*) in January or February. The ADR contains organ chapters, surveillance (descriptive) data, and time trends describing the nation's transplant system. SRTR aims to design a better way to access the data and plans to make regular updates, allowing users to query and create their own figures and tables.

Dr. Schaffhausen said that 25 volunteers were recruited through the SRTR simple data request log for data feedback sessions over Zoom. Individuals included patients, providers, OPOs, the Centers for Medicare & Medicaid Services (CMS), and researchers. Findings will be presented to the HCD Subcommittee for final review in early June 2021. In reviewing tool mock-ups, 1A, 1B, and 1C distinguished data by organ (waitlist, recipients), deceased donors, and living donors. Mock-ups 2A and 2B had a different hierarchy in which users could select organ or donor types. Mock-up 2B included stratification options by geography and age. Mock-up 3A included selections and output users might seek, such as time trends, plots, data tables, and maps. Survival curves are another option. Mock-up 3B was a bar plot example with potential use as a custom query tool.

Dr. Mannon clarified that the transplant data query system was meant to supplement rather than replace the ADR. Dr. Snyder confirmed this and said that the tool would allow the ADR in *AJT* to transition to include more special topics of particular relevance to each organ type. Drs. Khush and Mannon suggested incorporating a citation with the downloadable material. Mr. Pittman said that the ability to create granular data (eg, county-level) would create more interest. Mr. Knight said that the tool would help patients as well. Members said that the mock-ups were intuitive and easy to understand. SRTR plans to bring working versions to the committee later this year.

Identifying metrics to assess transplant system performance and inform decision-making

Dr. Snyder reviewed the Task 5 initiative and a slide deck the Steering Committee requested for communication purposes. It included topics on the National Organ Transplant Act (NOTA) which established SRTR; how SRTR was structured within the Department of Health and Human Services (HHS) and HRSA; and reporting requirements of the Final Rule, which state SRTR's purpose in making transplant system performance metrics available. It also included details on metrics available on the SRTR public website, data reports on the SRTR secure site, and the purpose, goals, and five-year timeline for Task 5. Patient focus groups will be discussed in the May Steering Committee meeting, focusing on a plan to facilitate the groups under the Patient and Family Affairs Subcommittee. HCD was also mentioned as an initiative to make data more engaging. Last, SRTR plans to host a public comment period for stakeholders before the consensus conference.

In regard to planning the Steering Committee meeting, speaker invitations will be sent at the end of 2021 instead of August 2021. SRTR wants to finish the public comment period before determining the speakers. The consensus conference is planned for the third week of July 2022. Also, certain stakeholders from the Steering Committee are assigned to present perspectives to the larger group.

Closing business

Hearing no other business, the meeting concluded. The next meeting is scheduled via teleconference for August 13, 2021.